Exhibit 2 Continued

Trial Declaration

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Hon. Patti B. Saris

TRIAL OF CLASS 2 AND CLASS 3 CLAIMS

TRIAL DECLARATION OF CATHLEEN DOOLEY

CATHLEEN DOOLEY declares under penalty of perjury as follows:

1. I am employed by Johnson & Johnson in its Washington, D.C. office as Executive Director of Federal Affairs. From June of 1995 through June of 2000 I was employed by Ortho Biotech as Director, and later Senior Director, for Reimbursement and Health Policy. In these roles have worked extensively with the Health Care Financing Administration ("HCFA"), the Centers for Medicare and Medicaid Services ("CMS"), and local Medicare Carriers on reimbursement issues relating to Procrit®. Earlier in my career I worked as a pediatric nurse and clinical researcher.

2. This testimony, insofar as it relates to events that occurred from 1995 to the present, is based on first-hand knowledge. The balance of my testimony, such as the testimony relating to drug pricing and reimbursement before 1995, is based on information I learned in the course of my employment at Ortho Biotech and Johnson & Johnson.

Procrit® and Epogen®

3. Ortho Biotech sells Procrit (epoetin alfa), a natural human hormone used to treat anemia. Ortho Biotech's right to sell Procrit is based on a Product License Agreement ("PLA") with its manufacturer, Amgen, Inc. Amgen sells epoetin alfa (referred to herein as "EPO") under the brand name Epogen. Except for the difference in brand names, Procrit and Epogen are identical.

4. Under the PLA, Amgen has the exclusive right to promote Epogen in the United States for use in dialysis patients. Ortho Biotech has the exclusive right to promote Procrit in the United States for use in the treatment of anemia caused by other conditions.

5. Although Amgen and Ortho Biotech are each obliged to promote EPO for their reserved medical indications, physicians are not bound by the terms of the PLA, and are

therefore free to administer either company's product to any patients they choose. Thus, physicians sometimes administer Procrit to dialysis patients, and Epogen to non-dialysis patients.

Reimbursement of EPO in Dialysis Centers

6. When EPO – whether in the form of Procrit or Epogen – is administered to dialysis patients, it is not reimbursed by Medicare on the basis of AWP. Rather, it is reimbursed under the government's End Stage Renal Disease ("ESRD") program. Prior to passage of the Medicare Modernization Act ("MMA"), EPO reimbursement under the ESRD program was set at a fixed, statutory rate which was unrelated to AWP. See 42 U.S.C. § 1395rr(B)(11)(B).

7. When Amgen introduced Epogen in 1989, the statutory reimbursement rate for EPO under the ESRD program was $40 for doses of 10,000 units or less, and $30 for any dose over that amount.[1] Epogen's list price at the time was $10 per 1000 units, and its AWP was 20% over the list price, i.e., $12 per 1000 units.

8. Congress revised the statutory reimbursement rate for EPO under the ESRD program when it passed the Omnibus Budget Reconciliation Act of 1990, which provided that, effective January 1, 1991, EPO administered in dialysis centers would be reimbursed at the rate of $11 per 1000 units.

9. Congress again revised the ESRD reimbursement rate for EPO in the Omnibus Budget Reconciliation Act of 1993. That law reduced the reimbursement rate from $11.00 per 1000 units, to $10.00 per 1000 units. Reimbursement for EPO under the ESRD program remained fixed at the statutory rate of $10.00 per 1000 units from January 1, 1994 through December 31, 2004.[2]

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[1] Office of Technology Assessment for the United States Congress, "Recombinant Erythropoietin: Payment Options for Medicare" (May 1990) ("OTA Report") at 4-5, 79. (Tab A) (DX 1046.)

[2] See 42 U.S.C. § 1395rr(b)(11)(B).

The Government's Study of Medicare Reimbursement Options for EPO

10. Procrit was not introduced to the market until January 1991. At that point, the government had been reimbursing Epogen under both the ESRD program and under Medicare Part B for 18 months, and EPO reimbursement policy had been the subject of careful study by the Office of Technology Assessment for the United States Congress ("OTA").

11. The OTA study, which was submitted to Congress in May 1990, is entitled "Recombinant Erythropoietin: Payment Options for Medicare" (May 1990) (Tab A) (DX 1046). The study report was prepared in response to a request from the House Ways and Means Committee, Subcommittee on Health, for an analysis of "alternative payment policies that Medicare might adopt to pay for [EPO]." (Id. at iii.)

12. The OTA report lays out several different reimbursement options under both the ESRD program and under Medicare Part B. With respect to EPO administered under the Part B program, one of the reimbursement options discussed in the report was to pay for it based on the published AWP. (Id. at 21.) Congress was told by the OTA that some Medicare Carriers were already using AWP "to derive an approved charge for physicians who administer [EPO] in their offices." (Id.) Congress was also told that "[a]verage wholesale prices, however, are usually list prices instead of the transaction prices that providers actually pay for pharmaceuticals." (Id.)

13. Although the OTA report was drafted at a time when Amgen's Epogen was the only EPO product on the market, the OTA anticipated the effect that Ortho Biotech's eventual entry into the market might have on EPO pricing. Specifically, the OTA predicted that Ortho Biotech, because it would be late to the market, might offer "price concessions and other benefits" in order to overcome Epogen's "brand loyalty" from being the "first brand on the market." (Id. at 71.)

Procrit Pricing

14. Procrit was launched in January 1991, approximately 18 months after the launch of Epogen. At the time of launch, the list prices for most Procrit NDCs were identical to the list prices previously established for Epogen, i.e., $10.00 per 1000 units. The list price on Procrit's 10,000 unit vial was slightly lower, i.e., $9.50 per 1000 units. Procrit's published AWPs, like Epogen's, were 20% higher than its published list prices, i.e., $12.00 per 1000 units (for the 2000, 3000 and 4000 unit vials) and $11.40 per 1000 units (for the 10,000 unit vial).

15. Shortly after Procrit's launch, Ortho Biotech began offering limited discounts on Procrit to retail pharmacies and physicians. During the class period, these price incentives generally ranged between 5% and 10% off of the list price, although some high-volume purchasing physicians could receive higher discounts. (Hospitals, managed care organizations, health plans and government purchasers also received discounts.)

16. I am informed that plaintiffs contend that the difference between Procrit's AWP and its annualized average selling price to the distributors who in turn sold to Part B providers was always less than 30%. Although I am not able to vouch for plaintiffs' calculations, they are consistent with what I know about Procrit's modest discounts.

Reimbursement of EPO in Physician Offices Under Medicare Part B

17. As noted above, when EPO – whether in the form of Procrit or Epogen – is administered by physicians to non-dialysis patients in an office setting, it is not reimbursed under the statutory ESRD rate. Rather, it is reimbursed under the provisions of Medicare Part B. Initially, as the OTA report stated, Part B reimbursement was based on the physician's

"reasonable charge."[3] Starting in 1992, however, it was reimbursed at 100% of AWP, and later, starting on January 1, 1998, at 95% of AWP.

18. When Procrit was introduced in January 1991 Medicare was still reimbursing Part B drugs based on the "reasonable charge" methodology. In June of 1991, after Procrit's list price and AWP had already been published, HCFA proposed changing the reimbursement rate on Part B drugs from a charge based method to "85 percent of the national average wholesale price of the drug (as published in the Red Book and similar price listings) . . . ."[4]

19. A number of providers, particularly oncologists, objected to HCFA's proposal to reimburse Part B drugs at 85% of AWP. After receiving comments on the proposed rule, HCFA adopted a final rule, effective January 1, 1992, providing for payment for physician-administered drugs at the lower of "estimated acquisition cost" or 100% of AWP.[5] Ortho Biotech did not submit comments on the proposed rule or play any role in seeking to persuade HCFA to reimburse Part B drugs at 100% of AWP rather than 85% of AWP.

20. Under HCFA's Final Rule, "estimated acquisition costs" were to have been determined, if at all, by surveys to be conducted by local Medicare Carriers of physician acquisition costs.

21. HCFA never conducted the surveys contemplated by its Final Rule. Rather, HCFA suspended its effort to survey estimated acquisition costs because it was advised

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[3] (Tab A) (DX 1046 at 5) ("For administration in a physician's office, Medicare pays for recombinant erythropoietin on a fee-for-service basis and sets approved charges based on customary, prevailing, and reasonable charges."); see also id. at 81 ("Unlike the case for dialysis facilities, for which the payment rate is $40 for up to 10,000 units of recombinant erythropoietin, Medicare pays the physician an approved charge on a fee-for-service basis; Medicare payment increases with the number of units administered to the patient and the physician's billed charge.").

[4] 56 Fed. Reg. 25800 (June 5, 1991).

[5] 56 Fed. Reg. 59502 (Nov. 25, 1991).

that the surveys could not be completed without first obtaining authorization from the Executive Office of Management and Budget, which authorization was never obtained.[6] Ortho Biotech took no action to prevent or deter HCFA from surveying estimated acquisition costs, and would not have been in a position to prevent or deter HCFA from carrying out such surveys had HCFA elected to do so. Because the surveys were never conducted, Part B reimbursement, including reimbursement for EPO administered outside the ESRD program, remained at 100% of AWP.

22. In 1997, Congress passed Balanced Budget Act ("BBA") of 1997. The BBA specified that, effective January 1, 1998, Part B drugs would be reimbursed based on the lesser of the amount charged by the provider, or 95% of "the average wholesale price."[7]

23. In the case of Procrit and Epogen reimbursed under Medicare Part B, most Medicare Carriers elected to base reimbursement on whichever product's AWP was lower. Thus, if Procrit's AWP was lower than Epogen's AWP, most Medicare Carriers would reimburse at Procrit's lower AWP. The same was true in reverse. If Epogen's AWP was lower than Procrit's AWP, most Carriers would reimburse based on Epogen's AWP.

24. HCFA (and later, CMS) continued to reimburse Part B drugs at 95% of AWP until the end of 2003, when Congress passed the Medicare Modernization Act. For most drugs, the MMA reduced the Part B reimbursement rate in 2004 to the rate HCFA had initially proposed in 1991 – 85% of AWP. For Procrit, however, the MMA reduced the 2004 reimbursement rate to 87% of AWP. Effective January 1, 2005, the MMA substituted a new

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[6] Memorandum from Charles R. Booth, Director, Office of Payment Policy, BPD, to All Associate Regional Administrators for Medicare 1 (Aug. 8, 1994) (Tab B) (DX 1059); Memorandum from Jill B. Merrill, Health Insurance Specialist, Medicare Operation, HCFA, to All Part B Carrier, PIL 94-435 (Aug. 12, 1994) (Tab C) (DX 1060.)

[7] Pub. L. 105-33 § 4556(a) (1997), codified in 42 U.S.C. § 1395U(o).

reimbursement formula – 106% of "average sales price" ("ASP").[8] Congress compensated for this downward revision in drug reimbursement to some extent by increasing physician service fees.

The Government's Understanding of Procrit Pricing

25. In 1997 and again in 2001, federal agencies issued reports that specifically referenced Procrit's selling prices compared to AWP.

26. The 1997 report is entitled "Excessive Medicare Payments for Prescription Drugs." (Tab D) (DX 1075). The report details the OIG's price-related findings with respect to 22 Part B drugs, including "Epoetin alpha [sic]" for "Non-ESRD Use." As noted below, the OIG concluded that the percentage savings that could be achieved by switching to "acquisition cost" reimbursement for Procrit was either the lowest or among the lowest of any of the 22 drugs studied.

27. The 1997 OIG report details the results of OIG's examination of AWP pricing compared to the prices offered in 1995 and 1996 by "wholesale drug companies and group purchasing organizations." (Id. at 4.) The OIG determined an "actual average wholesale price," and a "lowest" and "highest" wholesale price, and compared these prices to the "Medicare allowed amount." (Id. at 6.)

28. These OIG-determined prices are listed in Appendix B to the 1997 report. For HCPCS Code Q0136, which includes Procrit and Epogen, the OIG found the following prices as of 1995 and 1996 (id. at B-1 and B-2):

Q0136 (1995 Prices)			
Average Medicare Allowed Amount	Actual Average Wholesale Price	Lowest Wholesale Price Found	Highest Wholesale Price Found
$11.92	$9.92	$8.84	$10.70

[8] 42 U.S.C. § 1395w-3a(b).

Q0136 (1996 Prices)			
Average Medicare Allowed Amount	Actual Average Wholesale Price	Lowest Wholesale Price Found	Highest Wholesale Price Found
$11.93	$10.37	$9.31	$10.70

29. Based on these prices, the OIG calculated, in dollar and percentage terms, the savings that could be achieved if HCFA reimbursed based on "acquisition cost" as opposed to the then-existing Medicare Allowed Amount. (Id. at C-2 and C-3.) For the drugs in HCPCS Code Q0136, i.e., Procrit and Epogen, the percent savings would have been 17% in 1995 and 13% in 1996. (Id.)

30. In 1995, the percentage savings for the 22 drug codes studied ranged from 15% to 95%. In 1996, the percentage savings ranged from 13% to 92%. As the OIG notes, "[t]he savings for individual drugs ranged from 13 percent of allowances for three drugs (J9202, Q0136, J9185) to a high of 92 percent for leucovorin calcium (J0640)." (Id. at 7.)

31. Based on the differences between the Medicare reimbursement allowance and actual selling prices, OIG recommended that "HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate." (Id. at ii.) The OIG stated that, in its opinion, Congress' directive in the BBA of 1997 to reduce Part B reimbursement to 95% of AWP "is not a large enough decrease." (Id. at ii.) The OIG told HCFA that "further options to reduce reimbursement should be considered." (Id.)

32. HCFA was afforded an opportunity to respond to the OIG's recommendations, and its response is attached to the report as Appendix D. HCFA agreed with the OIG's recommendation that it should reexamine its use of AWP-based reimbursement, but noted that it had not received authority from Congress to base reimbursement on actual

acquisition cost. HCFA's Deputy Administrator, Nancy-Ann Min DeParle commented that (id. at D-3):

> We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.

33. A second study comparing Procrit's acquisition price to its AWP was published in 2001 by the General Accounting Office. (Tab E) (DX 1098.) This study, which was provided to Congress, reiterated the finding in prior government reports that AWPs were "'list prices' or 'sticker prices' set by drug manufacturers and used by Medicare to calculate payment rates" and, as such, "were not representative of the actual costs of these drugs to providers." (Id. at 1.)

34. The GAO study looked at 31 Part B drugs, including "Epoetin alpha [sic] for non-ESRD use." (Id. at Tables 4 and 5.) Based on its review of wholesale price lists, the GAO calculated an "Average widely available discount from AWP." In addition, the GAO used physician invoices to calculate a "Low volume billers' average discount from AWP." (Id.)

35. Table 4 shows that the "Average widely available discount from AWP" for Procrit was 15.2%. (Id. at Table 4.) The range for all drugs was 12.8% to 85.6%. Table 5 shows that the "Low volume [physician] billers' average discount from AWP" for Procrit was 22.1%. (Id. at Table 5.) The range for all drugs was 15.7% to 90.4%.

My Contacts with Officials From HCFA

36. From 1995 to the present, I have met numerous times with high-level HCFA officials in order to discuss Procrit reimbursement issues. I estimate that these meetings took place approximately 3 or 4 times a year. The officials I met with and spoke to included

Tom Scully, HCFA's Administrator; Nancy-Ann Min DeParle, the Deputy Administrator and subsequent Administrator; Mike Hash, an Acting Deputy Administrator; Tom Hoyer, a senior policy official; Kathy Buto, the Director of Policy Development; Kathy King, a Special Assistant to the Administrator; Jeff Kang, Medical Director; Steve Sheingold, Ph.D., a senior technical assistant; Bob Neimann, a senior analyst; Bart McCann, Medical Officer; and Tom Gustafson, Director of Payment Policy. Our meetings focused on several reimbursement issues relating to Medicare's coverage of non-ESRD EPO.

37. Among the first issues I recall discussing with HCFA was a policy decision made by the Medicare Carrier in Mississippi not to reimburse for EPO unless the Medicare patient's hematocrit (a measure of the patient's red blood cell count) was between 8 and 10. I helped to present Ortho Biotech's clinical arguments why this restriction was medically inappropriate and not in the best interests of anemic patients. HCFA was persuaded by our clinical arguments and the Mississippi Carrier's restrictive use policy was reversed. Another issue I recall discussing centered on our efforts to secure HCFA's approval for reimbursement of EPO administered to surgery patients.

38. In several of our meetings, HCFA personnel discussed Procrit's reimbursement rate. Some of their questions focused on the fact that the statutory reimbursement rate for EPO administered under the ESRD program was less than the rate utilized for physicians under Medicare Part B, notwithstanding that the drugs were exactly the same. On those occasions I recall explaining that the reimbursement rate was different because the drugs were reimbursed under different regulatory and statutory provisions.

39. I specifically remember Tom Scully, Nancy-Ann Min DeParle, Kathy King, Jeff Kang, and others telling me that they understood that doctors, particularly oncologists,

were profiting from the use of Part B drugs, including Procrit. I recall at least some of them describing AWP as "not an average" and "not a price," and commenting that AWP stood for "Ain't What's Paid." I recall discussing with them the fact that drug reimbursement based on AWP was being used to subsidize inadequate administration fees. I recall that HCFA officials told me that HCFA's long-term goal was to move away from AWP-based reimbursement in favor of a different system, such as, for example, a system based on actual acquisition costs or the Federal Supply Schedule.

40. These comments made it clear to me that HCFA understood that the published AWP figures that HCFA was using to set the reimbursement allowance under Medicare Part B were not actual average wholesale prices. Moreover, no one from HCFA ever told me that HCFA intended to refer to actual average wholesale prices when it proposed in its draft regulation in 1991 to reimburse physician-administered drugs at 85% of AWP, or that it intended such a meaning in the final draft of the 1991 regulation when reimbursement was set at 100% of AWP.

41. Similarly, no one within the government ever told me that Congress intended to refer to an actual average wholesale price when it used the phrase "average wholesale price" in the BBA of 1997. No one within the government ever said to me that published AWPs were supposed to reflect pricing incentives such as discounts and rebates. After the BBA of 1997 became law, no one within the government ever told me that Procrit's published AWP, which had always been 20% above the list price, should be changed to reflect discounts and rebates.

Ortho Biotech's Interest in Reimbursement

42. Ortho Biotech has always had an interest in ensuring that physicians receive adequate reimbursement for the Procrit they purchase and administer to their patients. Thus, from the outset, Ortho Biotech has worked closely with providers and with public and private payors to ensure that non-dialysis uses of EPO were eligible for reimbursement and that the process for securing reimbursement was as reliable and efficient as possible.

43. I monitored the reimbursement-related developments outlined above. However, except as discussed below, Ortho Biotech never attempted to influence the reimbursement formulae employed by public or private payors.

44. This is not to say that Ortho Biotech did not pay close attention to reimbursement issues. For example, Ortho Biotech retained McKinsey & Company to interview government and private payors to assess trends and developments that could affect Procrit's reimbursement. Two of McKinsey's reports have been marked by plaintiffs as Exhibits 243 and 338.

45. PX 243 is a McKinsey report titled "Shaping the Reimbursement Environment for Procrit." McKinsey presented the report to Ortho Biotech in June of 1999. McKinsey based its report on interviews with Ortho Biotech and Johnson & Johnson employees, executives at leading private payors, physicians, HCFA and state Medicaid officials, among others. (PX 243 at MDL-OBI00006644.)

46. McKinsey's June 1999 report notes, among other things, that the physician reimbursement ("physician economics") while "currently strong," was "likely to deteriorate, possibly creating a disincentive for physicians to administer Procrit." (MDL-OBI00006647.) McKinsey also noted that "a range of reimbursement pressures [including "AWP reduction"] threaten Procrit sales growth." (Id.) McKinsey chided Ortho Biotech for failing proactively to

try to influence the reimbursement environment. It urged Ortho Biotech to "move from a largely targeted, reactive strategy to one that proactively addresses a broader range of issues and constituents." (Id.)

47. McKinsey'S June 1999 report states that oncologists "have significant economic incentives to prescribe supportive care drugs such as Procrit, due to revenue and profits from stocking and administering." (Id.) There is little doubt that, in 1999, physician reimbursement under Medicare Part B was greater than acquisition cost (for all Part B drugs), resulting in physician "revenue" and, in some cases, "profits." Indeed, HCFA was acutely aware that physicians were being reimbursed at rates that exceeded acquisition cost, which is one of the reasons that HCFA pressed Congress to reform Part B reimbursement. Thus, one of the principal points of McKinsey's report was that payors were actively considering steps to reduce physician reimbursement, including 1) increasing the discount off of AWP from 5% to between 10% and 17%, and 2) mandating that reimbursement be set at "actual acquisition cost" or some other amount. (Id. at MDL-OBI00006654-55.) McKinsey's message to Ortho Biotech was that the company was not doing enough to try to influence the reimbursement environment, and that it should actively lobby physicians, advocacy groups, and public and private payors to ensure that physicians received adequate reimbursement so that patients could continue to be treated with supportive care medicines such as Procrit. (Id. at MDL-OBI00006659.)

48. McKinsey submitted a second reimbursement-related report in December 1999. (PX 334.) The December 1999 report also emphasized the possibility that Part B reimbursement would be reformed and the reimbursement rate might be lowered. McKinsey again advised us that the discount off of AWP might be increased "up to an additional 10%,"or that HCFA might decide to reimburse Part B drugs at the "Federal Supply Schedule" or at

"actual acquisition cost." (Id. at MDL-OBI00006795.) The report quotes a number of former and current HCFA and White House Officials as suggesting that an increase in the discount was more likely, as the change to actual acquisition cost was difficult and might not be feasible (id. at MDL-OBI00006798):

> "AWP-17% probably can be beat; but AWP-10% ... It's easier than defining AAC [Actual Acquisition Cost] or FSS [Federal Supply Schedule]."
>
> "This may just not be our most important battle right now... Rather than take on the industry en masse, I think we may see some one-off actions against select drugs."
>
> "Votes are not there this time around."
>
> "[Actual acquisition cost is a dead issue because] I don't think we have the votes."
>
> "We've got Y2K and much bigger issues."
>
> "Defining AAC is not easy and not worth the effort when you can just do an AWP change."

49. Ortho Biotech become more active in reimbursement policy issues in 2002 when Amgen introduced a new anemia treatment called Aranesp® (darboepoetin alfa). Aranesp is not subject to the PLA. Consequently, unlike Epogen, Aranesp competes directly with Procrit for use in the treatment of anemia in non-dialysis patients.

50. Aranesp's AWP at launch was 25% above its list price, whereas the AWPs for Procrit and Epogen were 20% above the list price. From a provider's perspective, this made Aranesp a potentially more attractive alternative to Procrit in the non-dialysis market where Medicare reimbursement was based on 95% of AWP.

51. Aranesp's 25% markup over list price changed the competitive dynamic. Before Aranesp was launched, Procrit's reimbursement needed to be adequate and reliable, but the amount of reimbursement was not particularly important from a competitive standpoint. That

was because, in the dialysis market, the reimbursement rate was fixed by statute and the profit Ortho Biotech earned from spillover sales of Procrit in the dialysis market had to be remitted to Amgen. Conversely, in the non-dialysis market, Amgen's profit from spillover sales of Epogen had to be remitted to Ortho Biotech. As a practical matter, this meant that neither Ortho Biotech nor Amgen had much of an incentive to try to capture market share from the other.

52. Moreover, as noted above, in the non-dialysis market, most Medicare Carriers had a policy of reimbursing EPO based on the lower of Procrit's AWP or Epogen's AWP. As a practical matter, this meant that neither company had an incentive to raise its AWP relative to the other.

53. Aranesp's introduction in 2002 changed this dynamic because, for the first time, physicians treating non-dialysis patients could chose between competing anemia therapies, one of which had a higher markup over the list price than the other. Assuming the dose-adjusted acquisition price of the two products was the same, a provider would receive higher reimbursement for the therapy with the 25% markup factor than for the therapy with the 20% markup factor. The difference favored Aranesp over Procrit.

54. In order to offset Aranesp's reimbursement advantage, Ortho Biotech considered several different options. One option, which we considered and which we even discussed with Tom Scully at HCFA, was to ask the price reporters to increase Procrit's markup factor from 20% to 25%. We rejected that option. We also considered offsetting Aranesp's reimbursement advantage by offering additional price incentives to non-dialysis providers, a move that would benefit physicians financially (at Ortho Biotech's expense) without adversely affecting payors. In fact, Ortho Biotech did implement new pricing strategies designed to retain

non-dialysis business that might otherwise have shifted to Aranesp, but these strategies were only partly successful.[9]

55. In the end, the option that we pursued most aggressively was to try to persuade CMS and state Medicaid agencies to eliminate Aranesp's reimbursement advantage by reimbursing Aranesp at the same rate they were applying to Procrit, i.e., to base their reimbursement of Procrit and Aranesp on the lower of their respective AWPs. This change, if adopted, would have reduced payor reimbursement costs.

56. In 2002, Ortho Biotech launched an initiative spanning several jurisdictions to try to persuade Medicare Carriers and State Medicaid officials to adopt what is known as a Least Cost Alternative ("LCA") policy with respect to Procrit and Aranesp. Under such a policy, payors can reimburse therapeutically similar therapies at the lowest applicable reimbursement rate. LCA policies lower reimbursement costs and curb any incentive that providers might have to choose between therapies based on economic considerations.

57. Two sample documents pertaining to Ortho Biotech's efforts to persuade payors to adopt LCA policies are marked as PX 338 and DX 2774 (Tab F).

58. PX 338 is a draft of a McKinsey report dated November 2002 entitled "Current Strategies." The document states that Ortho Biotech "is pursuing five strategies to reduce the role of economics in physician choice." (Ex. 338 at MDL-OBI00052885-86.) Among the five strategies are "**AWP reform** to reduce Amgen's ability to manipulate

[9] Some physicians switched to Aranesp, partly due to economic considerations. I understand, for example, that Dr. Linda Haegele, a oncologist practicing in Pennsylvania, has testified in this matter that she switched to Aranesp in 2005 in part because she lost money administering Procrit: "During 2005, I also made a shift in the erythropoietin that I prescribed for many of my patients from Procrit to Aranesp. In my professional opinion, Aranesp is equally effective as Procrit, but Aranesp saves me and my patients time. Moreover it was not financially feasible for me to provide Procrit to Medicare patients in 2005 because the Medicare reimbursement did not cover my acquisition cost. My practice lost $71.53 per shot of Procrit administered to Medicare patients." *Merits Report of Linda A. Haegele, M.D.* (Mar. 20, 2006) at ¶ 67.

reimbursement in D5/D6 [physician clinics]," and "**Least Costly Alternative (LCA)** to reduce both Aranesp's economic advantage and payor cost in D5/D6." (Id. at MDL-OBI00052886) (original emphasis.) The document accurately recites the fact that Johnson & Johnson supported AWP reform, in part because "[r]eplacing AWP-based reimbursement with reimbursement that accurately reflects acquisition cost would help ensure clinical criteria are the basis for drug selection," and also because Ortho Biotech perceived that "Amgen appears to be manipulating the AWP-based system to drive Aranesp sales in physician clinics." (Id. at MLD-OBI00052916.)

59. Some of Ortho Biotech's efforts to effectuate AWP reform are described in DX 2774 (Tab F), a collection of documents from 2002. The document entitled "Medicare Carrier LCA Strategic Plan" summarized the situation facing Ortho Biotech as follows (DX 2774 at MDL-OBI00043352) (original emphasis):

> **Pivotal Event:** NESP [Aranesp] has created a profit advantage due to the current AWP pricing of NESP. NESP is currently being marketed as a more profitable alternative to EPO.
>
> **Current Environment**: The AWP calculation for NESP is (List X 25%) and the AWP calculation for PROCRIT is (List X 20%). This disparity gives the providers that utilize red blood cell growth factors a greater profit if NESP is utilized. In a supportive care market where safety and efficacy are not differentiated for the two products, profitability may be the only difference between the two products. Therefore, the providers will switch to NESP due to the increase in profit.
>
> **OBP Strategic Position**: PROCRIT's dosing in the oncology market (40,000 units QW) is less expensive than the pricing of NESP given 2.25 mc/kg QW (quoted from the compendia reference).
>
> **Goal**: PROCRIT's pricing must be considered the least costly alternative for the two red blood cell growth factors by the Medicare carriers. Both drugs would be a covered benefit, however the AWP – 5% for EPO would be the amount paid for both products.

60. I met with numerous government officials, including Tom Scully at CMS, and with the local Medicare Carriers in Utah, Connecticut, South Carolina, Arizona, Mississippi, New York, California and Florida, to ask them to consider implementing LCA policies. As our documents reflect, I and others from the company presented clinical and cost comparisons "of EPO and NESP to the federal and state payers in order to demonstrate clinical and financial superiority for EPO." (Id. at MDL-OBI00043362.) Although some local Medicare Carriers, including the Carrier in Massachusetts, refused to allow Ortho Biotech to present arguments in favor of LCA, most of the local Carriers did agree to meetings. (Id.)

61. Our efforts to persuade the Medicare Carriers to adopt LCA policies were not particularly successful. The local Medicare Carrier in Utah was the only Carrier to implement a LCA policy applicable to NESP and EPO, but that policy was subsequently rescinded, we were told, due to political pressure from Senator Orrin Hatch and others.

62. Officials at CMS in Washington rejected the proposal because, we were told, it was "a local issue" for the State Medicare Carriers. (Id. at MDL-OBI00043372.) On other hand, we were told by some local Medicare Carriers that they could not implement LCA "because that is a direction that comes from CMS-central office," or "it was up to CMS to decide LCA." (Id.) One Carrier official indicated that, notwithstanding the "difference in cost of treatment particularly to patient co-pays," he needed to confer with the other Carriers and would "not implement LCA at this time." (Id. at MDL-OBI00043373.) Another Carrier official said he was "very cost conscious with Procrit and NESP," and "appreciated the cost calculator," but he had "serious reservations" because of confusion over the proper dose comparison. (Id. at MDL-OBI00043375) Another told us he would not implement LCA because "he is awaiting direction from CMS." (Id.)

63. Nevertheless, Ortho Biotech continued to press for AWP reform. DX 2776 (Tab G) is a "Talking Points" memorandum setting forth Ortho Biotech's position on AWP reform which states that "We support AWP reform, to move away from a system that creates inappropriate financial incentives for physicians to prescribe certain drugs." In addition, it states that "We believe the best approach is an ASP-based methodology, with no sunset." (original emphasis). Similar materials commenting on AWP reform are attached at Tabs H and I (DX 2775 and DX 2777).

The Memos I Wrote in the Mid-1990's

64. I understand that plaintiffs have identified as exhibits several memos I wrote in the mid-1990's which allegedly prove that Ortho Biotech violated Massachusetts law. I do not believe my memos are evidence of unlawful conduct.

65. In August 1996 I wrote a memo to Tom Amick, an Ortho Biotech executive, explaining the history of reimbursement under the ESRD program. (PX 339.) I noted (incorrectly) that HCFA was reimbursing EPO at $10.00 per 1000 units "across all indications" even though that rate was limited to ESRD. I noted that reimbursement for other Part B drugs was based on AWP, and that the government had "the right to change the reimbursement for any product by an arbitrary pricing decision or by survey . . . ."

66. On February 19, 1997, I wrote a memo regarding a drug reimbursement proposal submitted to HCFA by the Office of Management and Budget. (PX 369). Among other things, that OMB's proposal would have encouraged HCFA to conduct drug pricing surveys. I commented (id.):

> When the possibility of pricing surveys has occurred in the past, we have worked closely with ASCO to make sure that the actual acquisition cost is reflective of the costs incurred (i.e. syringes, storage, refrigeration, etc.). These costs are significant to the

> physicians' offices. I assume from the language that there is no consideration given to these indirect costs. The cost of medical and infusion supplies are considered incidental to treatment and theoretically payment is out of the windfall of the pharmaceuticals.
>
> Due to the fact the drugs are administered "incident to a physicians' services" under Medicare, the physician's office incurs significant up front outlay of cash - some of which may not be recovered due to wastage, spillage or indigent care.

67. Ortho Biotech's work with ASCO was not designed, in any way, to prevent Medicare from conducting surveys. Rather, our efforts were limited to ensuring that, if drug acquisition costs were to be surveyed, the surveys should define acquisition cost in a way that would include the costs incurred in administering Part B drugs, not just the ingredient cost.

68. I used the term "windfall" in my memo simply as a means of describing the difference between the Medicare reimbursement amount and the physician's acquisition cost. I noted in my memo that reimbursement greater than acquisition cost was justified, in part, by the fact that physicians must be paid more than acquisition cost in order to cover their expenses for unreimbursed or under reimbursed services. In other words, the "windfall" on drug reimbursement helped to make up for the "shortfall" on service reimbursement.

69. On April 3, 1997, I sent a similar memo to Shannon Salmon. (PX 365.) I again commented that proposed reductions in Part B reimbursement would "impact[] the windfall that the physician receives for the drug," which, in turn, could "impact some physician's prescribing pattern for a drug." I noted that reducing reimbursement would "expedite" the movement of Medicare drug administration from the physician's office to the hospital clinic." My point was simply that the proposed cuts in reimbursement could be significant, and that Ortho Biotech needed to be aware that changes in reimbursement were on the horizon.

70. On December 2, 1997, I wrote a memo to Gary Reedy, then Ortho Biotech's President, recommending that Ortho Biotech not increase Procrit's list price, and its

corresponding AWP, by more than 1.8% because I did not believe it was in Ortho Biotech's interest to price Procrit higher than Epogen. (PX 262.) I noted that EPO used in non-dialysis, because it was administered under Medicare Part B rather than under the ESRD program (see ¶¶ 6-9, above), was being reimbursed at $12.00 per 1000 units, whereas EPO administered under the ESRD program was reimbursed at $10.00 per 1000 units. I commented that HCFA was sensitive to price changes and that raising Procrit's list price above Epogen's list price might "trigger a drug survey by HCFA." I also noted that HCFA "reserves the right to pay the average acquisition cost established by surveying the market." I noted that HCFA conducted a survey, the consequence could be to reduce the reimbursement rate to "acquisition [cost], FSS or ESRD rate."

71. I offered a similar analysis in an email dated January 7, 1998. (PX 259.) I noted in my email that HCFA "initiated a pricing survey in 1994 that was cancelled mid-way as there was a regulatory glitch that they did not take into effect," and that "This was fortunate for us," because it meant that reimbursement on Procrit had not been reduced. I noted that HCFA had the right to survey providers and had already surveyed dialysis providers who were being reimbursed under the ESRD program. I noted that without a survey, the only way HCFA could reduce reimbursement would be to "require an invoice be submitted with each Medicare claim that is sent in," which would be "very cumbersome and the medical providers and Medicare carriers have rejected this."

72. I am advised that plaintiffs have highlighted my statement that "Right now they do not know what the cost is for different providers." As noted above, I knew from my conversations with Medicare officials that HCFA fully understood that AWP exceeded acquisition cost. I was merely pointing out that HCFA had not done survey to establish an

"estimated acquisition cost" for Part B drugs within the meaning of HCFA's 1991 regulation. I certainly believed that HCFA knew that physicians were receiving a margin over their acquisition costs. Indeed, the whole point of doing surveys would have been to lower the reimbursement amount by identifying EACs on Part B medications.

73. These memos to Ortho Biotech's management were intended to explain to management how Medicare Part B reimbursement worked, and to make clear to them that changes in the system, whether the result of a survey by HCFA or by legislative or regulatory fiat, would likely mean lower reimbursement for Part B drugs, including Procrit. I did not mean to suggest, nor did I believe, that the government was not aware that physicians were earning positive margins on Part B drugs, including Procrit, or that the government was unaware of the fact that Procrit was sold for less than AWP.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 11, 2006

Cathleen Dooley

Deposition Transcript

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
----------	)	01-CV-12257-PBS
This Document Relates to All Actions	)	
----------	)	

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

November 10, 2004
9:45 a.m.

Continued deposition of THOMAS HIRIAK, held at the offices of Hogan & Hartson, 875 Third Avenue, New York, New York, pursuant to notice, before Laurie A. Collins, a Registered Professional Reporter and Notary Public of the State of New York.

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perspective.
A. Again, differentiating between the two, the fact of reimbursement that it's widely available for Procrit, yes. The fact quantify here's how much you, Mr. Oncologist, can make on Procrit? The answer to that would be no.
Q. Without telling them exactly how much they can make, was it ever communicated to the practices that there was a favorable amount of reimbursement that will be provided to those who use Procrit?
MR. MANGI: Object to the form.
A. Again, maybe -- I don't mean not to answer your question. But if you're saying the fact of reimbursement that Medicare and private payors broadly --
Q. No, I'm talking about the amount.
A. No.
Q. The amount of reimbursement being favorable.
A. No.
Q. Not even speaking in general terms, it

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was never communicated to practices the economics -- the practice economics message that there's a favorable amount of reimbursement to be received for those who prescribe Procrit?
MR. MANGI: Again, objection to the form. I'm not sure what you mean by "favorable."
But has that word ever been used in conveying the message?
THE WITNESS: Not that I'm aware. The corporate direction has been clear. You can't in any way talk about profit margins -- product specialists can't be talking about that to oncologists.
Q. When did that come into effect?
MR. MANGI: Objection, asked and answered.
A. From the discussions I've had with people, that has always been in effect at Ortho Biotech.
MR. HOFFMAN: I'd like to mark as Exhibit Hiriak 018.
(Exhibit Hiriak 018 document, Bates

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stamped MDL OBI 00042743, marked for identification, as of this date.)
Q. Mr. Hiriak, the document that's been placed in front of you is Bates stamped MDL OBI 00042743. Do you see this document?
A. Yes.
Q. Have you seen this document before?
MR. MANGI: While the witness reviews it, is this a complete document or is this the first page of a document?
MR. HOFFMAN: It's my understanding this is the complete document, but if you'd like to check on that at a break --
MR. MANGI: I'm happy to accept your representation.
MR. HOFFMAN: -- and supplement the record, I have no problem with that.
A. No, I have not seen this before.
Q. You see that it was addressed to nephrology field sales? Do you see that?
A. Yes.
Q. And there's no "from." Do you know who

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would have created this document?
A. No.
Q. Read the document over for a moment. I'm going to ask you a couple questions about it.
(Pause.)
A. Okay.
Q. In the first paragraph of the document it says, Numerous reports have surfaced regarding Amgen's attempts to capture market share in key accounts by discussing the difference in AWP pricing between NESP and Procrit.
Do you see that?
A. Yes.
Q. Do you believe that was a true statement at the time it was made on or about November 20th, 2001, in this document?
A. Yes.
MR. BARLEY: I object to foundation.
Q. What's the basis of your belief that that's a true statement?
A. We did get reports about Amgen's product specialists in certain circumstances discussing AWP

MDL Trial Exhibits

ORIGINAL

Centocor

November 5, 1998

C. Kaye Riley, HCPCS Coordinator
Health Care Financing Administration
C5-08-27
7500 Security Blvd.
Baltimore, Maryland 21233-1850

Dear Ms. Riley:

I am pleased to submit the enclosed application for an alpha-numeric code in the Health Care Financing Administration Common Procedure Coding System (HCPCS) for Remicade™ (infliximab), a breakthrough drug for the treatment of Crohn's disease.

Remicade™ is indicated for the treatment of moderately to severely active Crohn's disease or the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy. It is also indicated as a treatment for patients with fistulizing Crohn's disease for reduction in the number of draining enterocutaneous fistula(s).

Following an expedited review, Remicade™ was approved by the FDA on August 24, 1998 and became available for wholesale purchase on October 5. Rapid and widespread adoption is expected of this new drug by gastroenterologists and other physicians who treat patients with Crohn's disease. To date, there have been 85 Medicare orders written for Remicade™. Therefore, I have included in the application a request for the assignment of a temporary code to be used pending approval of a new code for use beginning January 1, 2000.

A temporary code will facilitate claims processing and reduce the administrative burden with J3490 "Unclassified drugs". Specifically, a temporary code will eliminate the unnecessary and costly submission by physicians and review by carriers of written documentation regarding the drug administered, the dosage, the route of administration and the charge.

If you have any questions or require any additional information, please do not hesitate to contact me. In particular, if there is anything missing that would preclude consideration of the application at your next HCPCS meeting I would appreciate hearing from you as soon as possible.

I look forward to working with you on the development of the temporary and permanent codes needed to promptly and accurately report the use of this important advance in the treatment of Crohn's disease.

Sincerely,

Valerie Asbury, Director
Centocor, Inc.

Plaintiffs' Exhibit
261
01-12257-PBS

Centocor, Inc.•200 Great Valley Parkway•Malvern, Pennsylvania 19355-1307•Telephone (610) 651-6000•Facsimile (610) 651-6100

exc - 2

Health Care Financing Administration
Common Procedure Coding System (HCPCS)
Alpha-Numeric Coding Recommendation Format

Submitted by Centocor, Inc.
November 4, 1998

INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1. Item trade/brand name: REMICADE™
   Generic name: Infliximab
   FDA Classification: Chimeric (Human Murine) Monoclonal Antibody to Tumor Necrosis Factor (BB-IND 5389/ODA 95-924)

2. Describe the item in general terminology.

Description
Remicade is indicated in the treatment of patients with Crohn's disease, a chronic and debilitating disorder of the gastrointestinal tract that can greatly affect a patient's quality of life. The chronic inflammation of Crohn's disease is attributed to an imbalance between pro- and anti-inflammatory mediators. Pro- and anti-inflammatory mediators called cytokines regulate inflammation in Crohn's disease. Tumor necrosis factor-α and other pro-inflammatory cytokines predominate in Crohn's disease, resulting in chronic mucosal inflammation. Crohn's disease is neither medically or surgically curable. The goal of treatment is to induce and maintain remission, maintain quality of life, and minimize the toxicity of therapy.

Indication
REMICADE is indicated for treatment of moderately to severely active Crohn's disease or the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy. It is also indicated as a treatment for patients with fistulizing Crohn's disease for reduction in the number of draining enterocutaneous fistula(s).

Action
REMICADE is the first of a new class of agents that blocks activity of a key biologic response mediator called tumor necrosis factor alpha (TNF-α). It is believed that REMICADE reduces intestinal inflammation in patients with Crohn's disease by binding to and neutralizing TNF-α on the cell membrane and in the blood and by destroying TNF-α producing cells. This action may explain why REMICADE is a particularly effective inhibitor of TNF-α and why REMICADE has a rapid and substantial clinical benefit.

Dosage and Route of Administration
The recommended dose of Infliximab is 5 mg/kg given as a single intravenous infusion for treatment of moderately to severely active Crohn's disease in patients who have had an inadequate response to conventional therapy. In patients with fistulizing disease, an initial 5 mg/kg dose should be followed with additional 5mg/kg doses at 2 and 6 weeks after the first infusion.

How Supplied
Remicade (infliximab) lyophilized concentrate for injection is supplied individually-boxed single-use vials in the following strength: NDC 57894-030-01, 100 mg infliximab in a 20-ml vial.

3. Why are the current code categories inadequate to describe the item?

There are no current code categories that describe this item. Remicade™ is the first anti-TNF inhibitor to receive FDA approval.

Health Care Financing Administration
Common Procedure Coding System (HCPCS)
Alpha-Numeric Coding Recommendation Format

Submitted by Centocor, Inc.
November 4, 1998

4. List any local codes used by any third party payor to process the item.

We are unaware of any local codes in use by third party payers.

5. If specific codes are not being used, how are you currently billing for the item.

Code J3490 *Unclassified drugs* is being used. In addition, documentation of the drug administered, the dosage, route of administration and charge is submitted with the claim.

6. How long has this item been on the market?

Remicade™ was commercially available October 5, 1998.

The review timetable is listed below:

- December 30, 1997: Infliximab application submitted
- May 28, 1998: FDA voted unanimously to recommend approval of infliximab
- June 30, 1998: FDA issues a Complete Review letter for infliximab
- August 24, 1998: Centocor receives approval for Remicade™ from the FDA
- October 5, 1998: Product available for wholesaler purchase

➢ Although a time span of 6 months has not elapsed since the approval of Remicade™, Centocor is requesting with this application, that Remicade™ be granted a temporary J-code. Clinical data accumulated over the past 5 years was substantial enough for the FDA to grant Remicade™ an expedited review, resulting in product approval. Remicade™ is the first agent in its class (anti-TNF inhibitor) to be approved by the FDA. In addition, Remicade™ is the only FDA approved therapy for the treatment of Crohn's Disease.

7. How are you currently marketing this product or service?

Centocor sells direct to wholesalers and specialty distributors. Remicade™ is distributed nationally through these vendors.

8. Are Medicare carriers currently paying for this item?

Initial claims are just beginning to be filed. Discussions with Medicare carriers suggest that this product will be covered since Remicade™ is the only FDA approved therapy for Crohn's disease.

9. What is the total Medicare, medicaid and private business annual volume in sales and or rental for the six months of marketing experience prior to submitting the request for coding consideration? (Do not estimate or provide projections – the information provided must represent actual volume of sales for the drug/product for the specific period of time indicated.)

Six months worth of data is not available. However, between October 5 and November 3, 1998 eighty-five (85) Medicare orders for Remicade™ have been received.

10. Of the volume identified in #9, what is the percent of use in the following settings?

- Physician office
- Ambulatory Care Clinic
- Patient Home
- Inpatient Facility
- Other

(Based on discussions with clinicians, Remicade™ will be predominantly delivered as an outpatient infusion, either in the physician office or other ambulatory site: infusion center, endoscopy suite, or hospital outpatient department.)

11. What is the wholesale cost of the item?

Remicade™ AWP: $585.00 per 100mg vial

12. What is the retail cost of the item?

Remicade™ List Price: $458.00 per 100mg vial

13. List any manufacturers or suppliers of similar items.

None

14. Identify the difference between this item and that of competitors.

There are no competitors for Remicade™. Remicade™ is the first agent in its class (anti-TNF inhibitor) to be approved, and the only agent approved by the FDA for use in Crohn's disease.

Recommendation submitted by:

Valerie Asbury, RN, BSN
Director, Corporate Accounts
Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355-1307
Phone: (610) 651-6551
Fax: (610) 889-4769
Email: asburyv@centocor.com

Valerie Asbury 11/4/98

Valerie Asbury, Director, Corporate Accounts — Date

Order PROCRIT and Continue to Receive an 8% Rebate

All physician practices that purchase PROCRIT, a recombinant human erythropoietin, between January 4, 1993, and July 2, 1993, will continue to receive an 8% rebate.

To Receive Your PROCRIT Rebate...
Contact your pharmaceutical supplier or Ortho Biotech Customer Service at 1-800-325-7504. Send your invoices to:
MarketCheck Inc., 41 East 42nd Street, Suite 1522, New York, NY 10017.

In these and any other matters, your Ortho Biotech Product Specialist is always available for consultation.

Strength	Rebate/ vial	Rebate/ six-vial box
2000 units/mL	$1.60	$9.60
3000 units/mL	2.40	14.40
4000 units/mL	3.20	19.20
10,000 units/mL	7.60	45.60

Rebates based on Net Cost to Distributors.

Manufactured by Amgen Inc.
Thousand Oaks, California 91320-1789
Distributed by Ortho Biotech Inc.
Raritan, New Jersey 08869-0602
*Registered trademark of the distributor.

PURCHASING PHYSICIAN

Order Now to Receive Your Special Rebate

Strength	Current NDC Number/ Upcoming NDC Number[1]	Rebate/ vial[2]	Rebate/ six-vial box[2]
10,000 units/mL	0062-7401-03/ 59676-310-02	$42.50	$255.00
4000 units/mL	0062-7400-03/ 59676-304-02	16.00	96.00
3000 units/mL	0062-7405-03/ 59676-303-02	12.00	72.00
2000 units/mL	0062-7402-01/ 59676-302-02	8.00	48.00

[1] New NDC numbers will be phased in by year end 1993.
[2] Rebates based on net cost to distributors.

Save With Our New 25-vial Boxes

Strength	Current NDC Number/ Upcoming NDC Number[3]	Rebate/ vial[4]	Rebate/ 25-vial box[4]
10,000 units/mL	0062-7401-04/ 59676-310-02	$11.40	$285.00
4000 units/mL	0062-7400-04/ 59676-304-02	3.20	80.00
3000 units/mL	0062-7405-03/ 59676-303-02	2.40	60.00
2000 units/mL	59676-302-01[5] 02	N/A[5]	N/A[5]

[3] New NDC numbers will be phased in by year end 1993.
[4] Rebates based on net cost to distributors.
[5] The 2000-unit/mL strength will be available in 25-vial boxes by October 1, 1993. The rebate will be $1.50/vial, $40/25-vial box.

This rebate represents a discount on PROCRIT for Medicare, Medicaid, and certain other third-party healthcare programs and as such should be properly disclosed and reflected when making claims.

To Receive Your PROCRIT Rebate...

Send your invoices to: MarketChek Inc., 41 East 42nd Street, Suite 1522, New York, NY 10017.[6] To order PROCRIT, contact your pharmaceutical supplier.

Your Ortho Biotech Product Specialist is always available for consultation.

[6] Invoices must be dated between January 1, 1993, and December 31, 1993, and must be received by March 31, 1994.

PROCRIT*
EPOETIN ALFA

Manufactured by: Amgen Inc. Thousand Oaks, California 91320-1789
Distributed by: Ortho Biotech Inc. Raritan, New Jersey 08869-0670

*Registered trademark of the distributor.

REBATE AGREEMENT BETWEEN

CUSTOMER		SUPPLIER	
Customer Name	Mona Kaddis, MD	Ortho Biotech Products, L.P.	
Street Address	14 Prospect Street	700 US Highway 202 South	
City, State	Milford, MA 01757	Raritan, New Jersey 08869	
Phone No:	508-473-1190	Phone No.:	(908) 704-5133
Fax No:		Fax No.:	(908) 704-5346
Att:	Mona Kaddis	Att:	Elaine Kling
Effective Date:	May 1, 2001		
End Date:	April 30, 2004		

TABLE OF CONTENTS

DEFINITIONS

In this Agreement, the following terms shall have the meanings assigned to them below whenever they are printed with initial capitalization.

"Baseline Sales Volume" shall mean Sales Volume during the twelve (12) months immediately proceeding this Agreement Effective Date.

"Defined Product Market" shall mean the then current list of Drugs included in the therapeutic categories in which Product competes as published and distributed every calendar year by Supplier.

"DLP" shall mean Distributor List Price. For purposes of Rebate calculation, DLP shall mean Distributor List Price in effect on the first day of the relevant calendar year.

"Drug" shall mean any pharmaceutical, whether manufactured by Supplier or by any third party.

"Maintain Sales Volume" shall mean that current contract year Sales Volume meets or exceeds all previous contract year Sales Volumes and Baseline Sales Volume.

"NDC" shall mean National Drug Code.

"Participating Member" shall mean a physician or a name of a group of physicians whose Product purchases will be included in the calculation of Rebate payments.

"Product" shall mean PROCRIT.

"Product Credits" shall mean the total amount of Rebate credited to Customer for a calendar year at the Physician Distributor listed in Exhibit D.

"Product Market Share" shall mean the sum total of Product units utilized to patients for a year divided by the sum total of units utilized to patients for all Drugs in the relevant Defined Product Market.

"Rebate" shall mean a retrospective reimbursement based on the utilization of Product, to be credited to Customer under this Agreement.

"Right-of-First-Refusal (ROFR)" shall mean the following:

a. Customer and OBI will discuss the transition from a volume-based agreement to a market share-based agreement immediately upon a competing erythropoietic agent obtaining a respective FDA – approved nondialysis indication; and

b. Customer will provide OBI the opportunity to match any competing offer for a market share agreement. Upon OBI matching said offer, Customer will enter into the market share agreement with OBI.

"Sales Growth" shall mean a specific Sales Volume Performance Measurement for which a Customer can earn a Rebate.

"Sales Volume" shall mean the net purchases (List Price minus all discounts and rebates) of Product during a twelve month period of time.

"Units Utilized" shall mean the number of units dispensed to Patients for a given period.

"Utilization Report" shall mean a report, of the Units Utilized of each Drug in the Defined Product Market, including all brands or generics within the therapeutic category.

REBATE TERMS

1. **Prices.** All Products eligible under this agreement shall be sold by Supplier to Distributors at the DLP in effect at the time of sale. Supplier may change the DLP of any Product at any time and from time-to-time.

2. **Rebate Eligibility**
   a. Supplier shall pay to Customer the Rebates described in Exhibit A1 upon Customer's achievement of the performance measurements. Rebates shall be calculated off net purchases of Product.
   b. Upon mutual agreement of Customer and Supplier to exercise the Right-of-First-Refusal clause, Rebate Eligibility will convert to those requirements listed in Exhibit A2. Rebates shall be calculated off net purchases of Products.
   c. All Rebate payments will be provided in Product credits loaded to the Physician Distributor listed in Exhibit D.
   d. Rebate payments will only be calculated against purchases made by Participating Members listed in Exhibit C.

3. **Changes to Defined Product Markets**
   a. Upon conversion to the market share rebate described in Exhibit A2, Supplier retains the right to define or redefine any Defined Product Market based upon:
      i. the entry of a Drug into the market,

ii. the removal/discontinuation of a Drug from the market,
iii. a change in the indication of any Drug, or
iv. a modification by Supplier of their view of competitive Drugs against which Supplier's Products competes.

b. If there is a change in a Product's Defined Product Market, Supplier shall provide Customer with the revised Defined Product Market at minimum 30 days before the start of the contract year in which such change takes effect.

4. **Rebate Policies**
   a. During the use of the volume rebate described in Exhibit A1, Rebates shall be calculated on purchases made by Participating Members and reported to Supplier by Physician Distributors. Rebates shall be paid on a contract year basis.
   b. The aggregate Rebate for each contract year shall be paid by Supplier to Customer within 60 days after receipt by Supplier of all reports from Customer for such year as required by the Reports, Record Keeping and Audit provision herein.
   c. Supplier will provide a summary of the rebate calculations along with the rebate payment.
   d. All Product Credits utilized by Customer during the contract year will be included in the calculation of Sales Volume and Sales Growth numbers.

5. **Participating Member Eligibility.** Rebates shall not be paid for transactions involving:
   a. Participating Members residing outside of the fifty United States and the District of Columbia;
   b. Utilization by Participating Members for which Supplier is obligated to pay Rebates under prior agreements with commercial third parties or under any Federal or State government non-capitated benefit program including but not limited to Medicare or Medicaid, or
   c. Claims for utilization submitted later than 180 days after the end of a contract year.

6. **Reports, Record Keeping and Audit**
   a. During the use of the volume rebate described in Exhibit A1, Customer shall have no responsibility for submitting reports.
   b. During the use of the market share rebate described in Exhibit A2, Customer shall provide Supplier with a Utilization Report within 60 days after the end of each contract year. Notwithstanding the foregoing, Customer is under no obligation to provide any confidential patient information to Supplier.
   c. Customer warrants the accuracy of all reports submitted pursuant to this Agreement.
   d. During the term of this Agreement and for a period of three (3) years following the date of dispensing of Products by Participating Members, Customer shall keep and maintain accurate records with respect to the dispensing of Products by Participating Members reported by Customer pursuant to this Agreement.
   e. Supplier shall have the right, upon reasonable notice and during regular business hours, to audit the Customer's books and records to determine the accuracy of all reports and claims submitted and compliance with this Agreement.

7. **Own Use.** Customer warrants that all Products for which a Rebate will be claimed hereunder will be dispensed for use by Participating Members only.

PRODUCT SPECIFIC TERMS

Supplier's obligation to pay Rebates with respect to Product shall be subject to these Product Specific Terms:

1. **Nondialysis Use.** PROCRIT® (Epoetin alfa) is promoted for nondialysis use only. Supplier will not honor Rebate payments associated with this contract for any purchases made by Customer, for any Epoetin alfa usage by patients receiving dialysis treatment. Dialysis Centers are excluded from receiving rebates for PROCRIT under this agreement.
2. Supplier may discontinue or modify any Product at any time.

GENERAL PROVISIONS

1. **Changes in Products.** Supplier may discontinue or modify any Product at any time.
1. **Term** The term of this Agreement is set forth on the first page hereof. Either party may terminate this Agreement earlier by giving 30 days' notice to the other party. The provisions of these General Provisions shall survive termination of this Agreement.
2. **Notices** Any notice given in connection with this Agreement shall be sufficient if in writing and delivered by messenger or sent by postage prepaid mail or by facsimile to the address of the recipient as set forth on the cover page to this Agreement or as changed by the recipient by notice given hereunder. Notices or communications shall be effective when received by or otherwise known to the recipient or its legal representative. This provision is not intended to be exclusive, and any notice actually received shall be sufficient.
3. **Entire Agreement** This Agreement, including all of the sections and attachments listed in the Table of Contents, constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes all prior negotiations, agreements and understandings between the parties, whether oral or in writing, concerning the subject matter hereof. This Agreement may be modified only by an amendment signed by Customer and Supplier in the manner described in the Execution provision herein. The terms of any purchase order, invoice or similar document used to implement this Agreement shall not modify and shall be subject to this Agreement.
4. **Assignment** Neither party may assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other party. For purposes of this provision, assignment shall include any assignment by operation of law and any change in control of a party.

5. **Relationship of Parties.** The relationship of Customer to Supplier is that of independent contractor. This Agreement does not create a partnership, association, or other business entity. Neither party has the right to bind the other.

6. **No Third Party Beneficiaries** Unless specifically provided elsewhere herein, nothing in this Agreement is intended to benefit any person or entity not a party hereto.

7. **Publicity** Neither party shall permit or generate any publicity, advertising or promotion concerning this Agreement without the prior written consent of the other party.

8. **Confidentiality** Neither party shall use information contained in this Agreement for any purpose not contemplated by this Agreement, and each party shall restrict access to this Agreement and to information exchanged hereunder to personnel within its organization who need such access in order to perform their duties. The parties agree that the information contained in or related to the implementation of this agreement shall not be shared with any individuals or organizations not a signator to this agreement. The term "party" includes employees or consultants required to effectively implement this agreement as long as they individually have signed confidentiality agreements. Violation of this clause may lead to immediate termination of this agreement.

9. **Legal Changes** If any governmental entity shall enact or amend a law or adopt or amend a regulation, or if any governmental entity or court of competent jurisdiction shall adopt or amend an interpretation of a law or regulation, or if a judgment/award is rendered in litigation/arbitration, that has the effect of (a) prohibiting any right or obligation of a party under this Agreement, (b) making any such right materially less valuable or any such obligation materially more burdensome to a party, or (c) changing materially the economic conditions underlying any portion of this agreement, then such party may upon notice to the other party terminate immediately such right or obligation or portion of this Agreement insofar as such law, regulation or interpretation judgment or award applies.

In the specific instance of changes in published Medicare usage guidelines for PROCRIT, Supplier reserves the right to adjust, at its sole discretion, the Maintain Sales Volume and Sales Growth Performance Measurements described in the Rebate Schedule of this Agreement. Any adjustment in the hurdle would reflect substantial changes in PROCRIT reimbursement rates and coverage patterns. Any and all changes in Performance Measurements will be communicated to Customer in writing.

10. **Force Majeure** Noncompliance with any obligation under this Agreement for reasons of force majeure (such as: acts, regulations or laws of any government; war or civil commotion; destruction of production facilities or materials; fire, earthquake or storm; labor disturbances; failure of public utilities or common carriers; and any other causes beyond the reasonable control of the party affected) shall not constitute a breach of this Agreement.

11. **Execution** This Agreement will not be considered valid until all required signatures as indicated below have been affixed.

12. **Pricing and Discount Disclosure**

a. Customer and Participants are hereby advised that they are obligated to:

i. fully and accurately disclose the cost of all Products purchased hereunder – including any discounts, rebates, or other price reductions – in cost reports or claims for reimbursement by Customer and Participants to Medicare, Medicaid, or other health care programs requiring such disclosure, and

ii. provide such documentation to representatives of the Secretary of the Department of Health and Human Services and state agencies upon request.

b. Unless noted otherwise, the value of any Product listed as $0.00 on any invoice may constitute a discount which should also be evaluated by Customer and Participants when filing such reports.

c. The value of any item which is designated as or known to Customer or Participants to constitute a sample should not be included as a discount for cost-reporting purposes and no reimbursement for such items should be sought from third party payers.

d. Customer and Participants are advised to retain this Agreement, invoices and any later documentation provided by Supplier regarding the existence and amounts of discounts, rebates or other price reductions.

e. Customer and Participants may request additional information from Supplier in order to meet their reporting or disclosure obligations by writing to the address in the introduction.

13. **DISPUTE RESOLUTION** ANY CONTROVERSY OR CLAIM ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE BREACH THEREOF, SHALL BE SETTLED BY ARBITRATION IN ACCORDANCE WITH THE COMMERCIAL ARBITRATION RULES OF THE AMERICAN ARBITRATION ASSOCIATION, AND JUDGMENT UPON THE AWARD RENDERED BY THE ARBITRATOR MAY BE ENTERED IN ANY COURT HAVING JURISDICTION THEREOF. THE ARBITRATION SHALL BE HELD IN NEW JERSEY AND THE ARBITRATOR SHALL APPLY THE SUBSTANTIVE LAW OF NEW JERSEY, EXCEPT THAT THE INTERPRETATION AND ENFORCEMENT OF THIS ARBITRATION PROVISION SHALL BE GOVERNED BY THE FEDERAL ARBITRATION ACT. THE ARBITRATOR SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES, AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES IN ARBITRATION OR IN JUDICIAL PROCEEDINGS. THE PARTIES AGREE TO COMPLETE ALL ARBITRATION PROCEEDINGS WITHIN SIX MONTHS OF THE INITIATION OF THE ARBITRATION.

SIGNATURES

IN WITNESS WHEREOF the parties have caused this Agreement to be executed by their duly authorized officers or representatives.

SUPPLIER	CUSTOMER
6/7/01	5/31/01
Thomas C. Hirlak Director, Strategic Accounts Date	[Customer Name & Title] Date

Mona Kaddis, MD

EXHIBIT A1: VOLUME-BASED REBATE SCHEDULE

CONTRACT YEAR	PERFORMANCE REBATES		
	Performance Measurement	Contract Year Sales Volume	Rebate Percentage
1	ROFR + Maintain Sales Volume	$50,000 – 700,000 $700,001 – 3 Million $3 Million+	0.25% 0.50% 0.75%
	Sales Growth	Sales Over $442,757	0.25%
2	ROFR + Maintain Sales Volume	$50,000 – 700,000 $700,001 – 3 Million $3 Million+	0.25% 0.50% 0.75%
	Sales Growth	Sales Over $495,888	0.25%
3	ROFR + Maintain Sales Volume	$50,000 – 700,000 $700,001 – 3 Million $3 Million+	0.25% 0.50% 0.75%
	Sales Growth	Sales Over $545,476	0.25%

GENERAL NOTES

1. A specific Rebate percent shall be associated with each Performance Measurement and such Rebate percent shall be earned by Customer upon Customer's performance meeting the conditions of such Performance Measurement and all other applicable conditions in this Agreement.

2. A Performance Rebate multiplier is available to Customer in Contract Year 2 and 3.
   a. Year 2: If the ROFR + Maintain Sales Volume Performance Measurements are achieved in Contract Years 1 and 2, then the Rebate Percentages for Year 2 will be multiplied by 1.5. If the earned Rebate Percentage during Year 2 is 0% but Customer's total contract purchases exceed the sum of the sales growth hurdles to date, then Customer will receive the following rebate percentages based upon Contract Year 2 Sales Volume.

CONTRACT YEAR 2 SALES VOLUME	REBATE PERCENTAGE
$50,000 - $700,000	0.5%
$700,001 – 3 Million	0.75%
$3 Million+	1.0%

   b. Year 3: If the ROFR + Maintain Sales Volume Performance Measurements are achieved in all Contract Years, then the Rebate Percentage for Year 3 will be doubled. If the ROFR + Maintain Sales Volume Performance Measurements are achieved in two out of the three Contract Years, then the Rebate Percentage for Year 3 will be multiplied by 1.5. If the earned Rebate Percentage during Year 3 is 0% but Customer's total contract purchases exceed the sum of the sales growth hurdles to date, then Customer will receive the following rebate percentages based upon Contract Year 3 Sales Volume.

CONTRACT YEAR 3 SALES VOLUME	REBATE PERCENTAGE
$50,000 – 700,000	0.5%
$700,001 – 3 Million	0.75%
$3 Million+	1.0%

EXHIBIT A2: MARKET SHARE-BASED REBATE SCHEDULE

CONTRACT YEAR SALES VOLUME	MARKET SHARE	REBATE %
$50,000 – 700,000	Equal to or greater than 85%	1.0%
$700,001 – 3 Million	Equal to or greater than 85%	1.5%
$3 Million+	Equal to or greater than 85%	2.0%

GENERAL NOTES

1. A specific Rebate percent shall be associated with each Performance Tier, and such Rebate percent shall be earned by Customer upon Customer's performance meeting the conditions of such Performance Tier and all other applicable conditions in this Agreement.

2. Nondialysis Use PROCRIT® (Epoetin alfa) is promoted for nondialysis use only. Supplier will not honor Rebate payments associated with this contract, for any purchases made by Customer, for any Epoetin alfa usage by patients receiving dialysis treatment. Dialysis Centers are excluded from receiving rebates for PROCRIT under this agreement.

EXHIBIT B: PRODUCT LIST

NDC	Product	Generic Description	Strength	How Supplied	Selling Unit of Measure
59676-302-01	PROCRIT	Epoetin alfa	2,000 u/1ml	1ml vials	6
59676-303-01	PROCRIT	Epoetin alfa	3,000 u/1ml	1ml vials	6
59676-304-01	PROCRIT	Epoetin alfa	4,000 u/1ml	1ml vials	6
59676-310-01	PROCRIT	Epoetin alfa	10,000 u/1ml	1ml vials	6
59676-312-01	PROCRIT	Epoetin alfa	10,000 u/2ml	2ml vials	6
59676-320-01	PROCRIT	Epoetin alfa	20,000 u/1ml	1ml vials	6
59676-340-01	PROCRIT	Epoetin alfa	40,000 u/1ml	1ml vials	4
59676-302-02	PROCRIT	Epoetin alfa	2,000 u/ml	1ml vials	25
59676-303-02	PROCRIT	Epoetin alfa	3,000 u/ml	1ml vials	25
59676-304-02	PROCRIT	Epoetin alfa	4,000 u/ml	1ml vials	25
59676-310-02	PROCRIT	Epoetin alfa	10,000 u/ml	1ml vials	25

EXHIBIT C: LIST OF PARTICIPATING MEMBERS

In the LIST OF Participating Members, Customer and Supplier will identify the physicians whose PROCRIT purchases will count towards the performance hurdles and on whose purchases performance rebates will be paid:

PHYSICIAN NAME	IDENTIFICATION (e.g. DEA#)	ADDRESS
Mona Kaddis	AK6872554	Mona Kaddis, MD Milford, MA

In addition, Customer and Supplier will identify the name of practices whose PROCRIT purchases will count towards the performance hurdles and on whose purchases performance rebates will be paid:

PRACTICE NAME	IDENTIFICATION (e.g. DEA #)	ADDRESS

EXHIBIT D: PHYSICIAN DISTRIBUTOR

In Exhibit D, Customer shall provide Supplier with the name of the physician distributor at which Customer wants all rebates, in the form of PROCRIT product credits, reported and paid.

Name of Physician Distributor: OTN

Name of Secondary Physician Distributor: _____

◆ **Memorandum**

ORTHO BIOTECH

To: Nephrology Field Sales **Date:** November 20, 2001

From: **cc:**

Subject: Competitive Position

Numerous reports have surfaced regarding Amgen's attempts to capture market share in key accounts by discussing the difference in AWP pricing between NESP and PROCRIT. By doing so, they seek to entice key accounts to switch products based solely on the difference between AWP price and the cost of acquisition (margin).

Recently, the United States General Accounting Office issued a report on behalf of the House Ways and Means Committee, the Senate Finance Committee and House Committee on Energy and Commerce making recommendations to begin reimbursing providers for part B-covered drugs and related services at levels reflecting providers' acquisition costs.

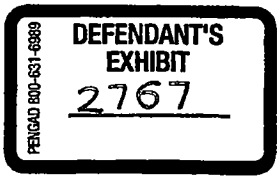
This would be a departure from the current methodology of using AWP pricing minus 5% as the benchmark for reimbursement.

What does this mean to you?

In the event an account approaches you and wants to discuss "profitability" you should address the issue with facts regarding the changing reimbursement environment and our continued support of Healthcare Compliance initiatives. The government has not yet approved the recommended changes; however, in all likelihood they will be in effect in 2002 or early 2003.

In conclusion, there are several issues that should be discussed with these accounts:

- It is absolutely inappropriate to sell product based upon the difference between AWP and acquisition price
- Reimbursement changes are on the horizon that will affect their decision
- By switching to a more expensive product (NESP), the patients will have to pay a higher co-pay and the healthcare system will have to bear the brunt of a more expensive therapy
- There is a significant cost involved with switching any product, whether it be training or time



UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Hon. Patti B. Saris

PLAINTIFFS' SUPPLEMENTAL RESPONSE TO THE J&J DEFENDANTS' REQUESTS FOR ADMISSION AND INTERROGATORIES CONCERNING REMICADE®

Plaintiffs submit this Supplemental Response to the Johnson & Johnson Defendants' Requests for Admissions and Interrogatories as follows.

OBJECTIONS

1. This Supplemental Response is made while Plaintiffs' Objections to the November 9, 2005 ruling of Magistrate Judge Bowler are pending. Plaintiffs reserve the right to withdraw this Supplemental Response based on the disposition of the Objections.
2. The Responses contained herein are based on the data available to Plaintiffs as of this date. Plaintiffs reserve the right to amend or modify these Responses if additional data becomes available.
3. Plaintiffs object to the J&J Defendants' "definitions" to the extent they create obligations broader than what is required by the Federal Rules of Civil Procedure.
4. Plaintiffs object to the J&J Defendants' Requests and Interrogatories to the extent they seek information which is the subject of expert analysis and opinion.

5. Plaintiffs object to the J&J Defendants' Interrogatories to the extent they seek the factual basis for any denial, when such denial is based on the absence of facts or information.

REQUEST TO ADMIT NO. 1:

Admit that Centocor began selling Remicade® in 1998.

RESPONSE TO REQUEST TO ADMIT NO. 1:

Admitted.

INTERROGATORY NO. 1: If your response to Request to Admit No. 1 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY 1:

Not Applicable.

REQUEST TO ADMIT NO. 2: Admit that from 1998 to the present, the published AWP for Remicade® has been 130% of the published WAC for Remicade®.

RESPONSE TO REQUEST TO ADMIT NO. 2:

Admitted.

INTERROGATORY NO. 2: If your response to Request to Admit No. 2 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 2:

Not applicable.

REQUEST TO ADMIT NO. 3: Admit that from 1998 to the present, Centocor, Inc. has not paid rebates on Remicade® to physicians who purchase or dispense Remicade®.

RESPONSE TO REQUEST TO ADMIT NO. 3:

Admitted. This Response is based on the definition of rebates articulated at the November 9, 2005 hearing, see transcript pages 10-11, and based on the rebate data produced by Centocor to date.

INTERROGATORY NO. 3: If your response to Request to Admit No. 3 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 3:

Not applicable.

REQUEST TO ADMIT NO. 4: Admit that from 1998 to the present, Centocor, Inc. has not paid rebates on Remicade® to pharmacy benefit managers.

RESPONSE TO REQUEST TO ADMIT NO. 4:

Admitted. This admission is based on the definition of rebates articulated at the November 9, 2005 hearing, see transcript pages 10-11. This admission is also based on the rebate data produced by Centocor to date.

INTERROGATORY NO. 4: If your response to Request to Admit No. 4 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 4:

Not applicable.

REQUEST TO ADMIT NO. 5: Admit that from 1998 to the present, the only rebates that Centocor, Inc. has paid on Remicade® have been rebates paid to persons or entities that reimburse for Remicade®, such as Health Maintenance Organizations and Preferred Provider Organizations.

RESPONSE TO REQUEST TO ADMIT NO. 5:

Denied. This Response is based on the definition of rebates articulated at November 9, 2005 hearing, see transcript pages 10-11. This response is based on the rebate data produced by Centocor to date.

INTERROGATORY NO. 5: If your response to Request to Admit No. 5 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 5:

The electronic rebate data produced by Centocor does not show payments to HMOs, but does show rebate payments to hospitals and others that are apparently not Preferred Provider Organizations. Some of these payments appear to be called "VOO" by Centocor. Centocor's electronic data was discussed at the deposition of Centocor's Michelle Murphy. This Response is based on the definition of rebates articulated at the hearing of November 9, 2005.

REQUEST TO ADMIT NO. 6: Admit that from 1998 to the present, the rebates that Centocor, Inc. has paid on Remicade® have reduced the net reimbursement cost of Remicade® for those payors that have received rebates.

RESPONSE TO REQUEST TO ADMIT NO. 6:

Admitted in part, denied in part. Admitted that, in theory, those payors who actually received rebates from Centocor incurred a reduction in the Net Reimbursement Cost of Remicade, as that term is defined by Centocor. It is denied that payors actually received any rebates on Remicade. This response is based on the limitations of the Request for Admissions as stated by the parties at the November 9, 2005 hearing.

INTERROGATORY NO. 6: If your response to Request to Admit No. 6 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 6:

The electronic rebate data produced by Centocor does not indicate what rebates, if any, were ultimately paid to payors. This response is based on the limitations of the Request for Admissions as stated by the parties at the November 9, 2005 hearing.

REQUEST TO ADMIT NO. 7: Admit that from 1998 to the present, the rebates that Centocor, Inc. has paid on Remicade® have reduced the spread.

RESPONSE TO REQUEST TO ADMIT NO. 7:

Objection. The term "spread" as defined by Centocor is vague and ambiguous, and differs substantially from the definition of spread used by Plaintiffs in this litigation. Further, the Request is objectionable as a burdensome contention interrogatory that would require plaintiffs to research sources of documents in the possession of J&J, when J&J could just as easily collected this information and presented the basis for the RFA. This Request also seeks an admission which is not relevant.

INTERROGATORY NO. 7: If your response to Request to Admit No. 7 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 7:

Objection. The term "spread" as defined by Centocor is vague and ambiguous, and differs substantially from the definition of spread used by Plaintiffs in this litigation. Further, this Interrogatory also seeks information which is not relevant.

REQUEST TO ADMIT NO. 8: Admit that from 1998 to the present, the spread on Remicade® has not exceeded the difference between its published WAC and its published AWP for all persons or entities that reimbursed Remicade at or below its AWP.

RESPONSE TO REQUEST TO ADMIT NO. 8:

Denied.

INTERROGATORY NO. 8: If your response to Request to Admit No. 8 contains a denial, in whole or in part, describe the basis for your denial, and identify all documents and testimony that you rely on to support your denial.

RESPONSE TO INTERROGATORY NO. 8:

Objection. The term "spread" as defined by Centocor is vague and ambiguous, and differs substantially from the definition of spread used by Plaintiffs in this litigation. Further, this Interrogatory also seeks information which is not relevant. The Court ruled on November 9, 2005 that Plaintiffs did not have to provide their calculation of the "net acquisition cost" for Remicade, which is a component of the "spread" as defined by Centocor. Plaintiffs have provided herein the WAC and AWP prices for Remicade as well as an aggregate calculation of "net reimbursement cost", which is another component of "spread".

INTERROGATORY NO. 9: From 1998 to the present, state each published WAC and each published AWP for Remicade®, and the effective date of each change in Remicade®'s WAC and AWP.

RESPONSE TO INTERROGATORY NO. 9:

A listing of the WAC and AWP pricing for Remicade, based on the information currently available to Plaintiffs, is attached as Exhibit A.

INTERROGATORY NO. 10: State the ASP for Remicade® for each of the time intervals between the changes in Remicade®'s WAC and AWP identified in response to Interrogatory No. 9.

RESPONSE TO INTERROGATORY NO. 10:

A listing of the ASP for Remicade, calculated annually, is attached as Exhibit B. These calculations are based on the best available data provided to Plaintiffs by defendant and subject to all caveats and qualifications relating to such calculations as set forth more fully in Plaintiffs' forthcoming expert report. Plaintiffs reserve the right to supplement these calculations in light of any additional information that is provided to Plaintiffs.

INTERROGATORY NO. 11: State the average net reimbursement cost and the average net acquisition cost for Remicade® for each of the time intervals between the changes in Remicade®'s WAC and AWP identified in response to Interrogatory No. 9.

RESPONSE TO INTERROGATORY NO. 11:

Objection. This Interrogatory seeks information which is not relevant, nor calculated to lead to the discovery of admissible evidence. The Court ruled on November 9, 2005 that Plaintiffs did not have to provide their calculation of the "net acquisition cost" for Remicade.

Without waiving such objections, Plaintiffs state that the average net reimbursement cost for all drugs in this litigation, including Remicade, for private, non-governmental payors, is 97.5% of AWP. The net reimbursement cost for governmental payors is determined by statute.

Dated: December 13, 2005.

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CO-LEAD COUNSEL FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2005 I caused a true and correct copy of the Plaintiffs' Supplemental Response to J&J Defendants' Requests for Admission and Interrogatories Concerning Remicade® to be served on all counsel of record by electronic service via Lexis/Nexis, pursuant to Case Management Order No. 2.

/s/John Macoretta
John Macoretta

EXHIBIT A

REMICADE PRICING HISTORY

Date	AWP	WAC
At Launch – September 1998	$585.00	$450.00
Price Increase – June 18, 1999	$611.33	$470.25
Price Increase – April 1, 2000	$641.28	$493.29
Price Increase – November 3, 2000	$665.65	$512.04
Price Increase – June 6, 2001	$691.61	$532.00

EXHIBIT "B"

Remicade Annual ASPs

NDC	Description	1998	1999	2000	2001	2002	2003
57894003001	C168J REMICADE 1PCK US PD	$447.26	$458.23	$486.17	$508.25	$518.65	$514.98